UNIVERSITY OF CALIFORNIA, SAN FRANCISCO

MEMORANDUM OF UNDERSTANDING AND AGREEMENT
RECOMBINANT DNA

Base #_____

Supplement #_____

he information in this MUA may be made public upon proper request.

A) DESCRIPTION:

Below is a layman's description of the experiments being conducted which involve recombinant DNA molecules and the significance of this research. On the right is an assessment of the physical and biological containment required for the experiment.

Description:	Containment P	Containment HV
Recombinant DNA molecules containing sequences derived from papovaviruses and retroviruses will be introduced into eukaryotic cells by transfection under conditions which do not permit production of virus. The papovavirus DNA (simian virus-40 or polyoma virus DNA) will be obtained either from infected mammalian cells or from EK host vector systems in which it has been previously cloned. The DNA will be disabled by the insertion of foreign DNA into regions of the genome essential for virus replication; in some cases, a portion of the papova virus genome will also have been deleted. The retrovirus DNA will consist of subgenomic portions of the DNA of avian or murine retroviruses which in some cases will be linked to the eukaryotic cell DNA to which it is joined after natural infection. The retrovirus DNA (and any adjacent cellular DNA) will have been cloned in EK host vector systems and characterized by restriction mapping and molecular hybridization. The recombinants between papovavirus and retrovirus DNA to be used for transfection may, in some cases, be cloned in EK host vector systems and characterized by restriction mapping and molecular hybridzation prior to administration to eukaryotic cells. The papovavirus-retrovirus recombinant DNA's will in most cases include sequences derived from the EK host vector systems used in the primary cloning of either DNA and/or in the secondary cloning of virus-virus recombinants. The recombinant DNA's will be used under P2 conditions to transfect cultured cells which are not permissive for replication of the involved papovavirus(e.g. cells other than murine cells for recombinants containing polyoma virus DNA, and cells other than simian cells for recombinants containing SV40 DNA). Successful transfection will be scored by morphological transformation of the recipient cells. When transformed recipients have been characterized with respect to acquired recombinant DNA and shown to be free of such DNA replicating independently of the host genome, the cells will be propagated under P1 conditions.	P2/P1	Not applicable

SHIPMENT AND TRANSFER:
I agree to comply with the NIH requirements pertaining to shipment and transfer of recombinant DNA materials as stated in the December 22, 1978 Federal Register and in supplemental instructions provided the IBC and me.

Date___/___/___

Base #_____

Supplement #_____

CERTIFICATION SECTION:

1) PRINCIPAL INVESTIGATOR:

I have read and become familiar with the NIH revised guidelines regarding recombinant DNA published in the December 22, 1978 Federal Register and I agree to abide by their provisions to the best of my ability. I agree to abide by all subsequent instructions issued by NIH and received by me. I agree to inform those working on this project about the availability of health surveillance and to ensure that they have received training in good laboratory practices. I agree to immediately inform the IBC of any significant research related accidents and illnesses. I agree to submit this study to institutional review at least annually. I agree to gain interim approval of modifications to the study, the facilities or the procedures.

Date 8-17-79 Signature [signature]

Date_____ Signature_____

Date_____ Signature_____

2) BIOSAFETY COMMITTEE:

The Biosafety Committee has reviewed this MUA and has approved it. It has been found to be in compliance with the NIH guidelines dated December 22, 1978 and with the subsequent instructions which have been received by the IBC. The date the MUA was approved is _____.

The Principal Investigator is required to comply with the NIH requirements pertaining to health surveillance as stated in the December 22, 1978 Federal Register. The investigators are required to inform those on the project that they have the option/requirement of seeking the services of the Employee Health Service.

Date_____ Signature_____
Chairman, IBC, UCSF

3) INSTITUTIONAL OFFICIAL:

The University of California, San Francisco retains responsibility for the procedures to be performed under this MUA. The requirements stated in the NIH guidelines published in the Federal Register of December 22, 1978 and in subsequent instructions received by this institution will be transmitted to the IBC.

Date_____ Signature_____
Shirley S. Chater
Vice Chancellor
Academic Affairs, UCSF

MUA SUPPLEMENT - INTERNAL DOCUMENT

Instructions: Submit 13 copies of pages 1 and 3 stapled in 13 sets for distribution. Submit 1 copy of the signature page.

Base # _____ Supplement _____

A) IDENTIFICATION:

Prin Investigator HE Varmus

Mailing Address HSE 465 Phone x2824 Secretary B.Cook Phone x2824

Co/other Investigators (optional) JM Bishop

B) SCIENTIFIC INFORMATION:

Host: Various mammalian tissue culture cells

Vector: Not applicable

Species source of DNA: Various avian and mammalian cells

Purity of DNA: Greater than 99% x Less than 99% x

If greater than 99% is claimed, provide the basis for the claim:

In some cases, the DNA to be used will be cloned in EK host vector systems and characterized by restriction mapping and molecular hybridization

Facilities: Room(s) HSE 457 HSE 469

Classification P2 P1

C) SUBMISSION DATA:

x This MUA should be submitted to NIH for approval.
_____ This MUA should be submitted to NIH for registration.
_____ This MUA should be submitted elsewhere. See below.

This MUA is:
x New
_____ Renewal of MUA base # _____
(x) Modification of MUA base # _____
_____ Other _____ Submitted for transmission to new agency or for new grant.
_____ Other _____

D) SUPPORT DATA:

1) PI H.E. Varmus Agency NCI Grant # 19287

Grant title: Molecular Biology of mouse mammary tumor virus

2) PI _____ Agency _____ Grant # _____

Grant title _____

Address to which MUA should be sent by IBC:
(1) Carrett Keefer (2) HSE 465 (3) ORDA
Div. of Cancer Cause and Prevention
NCI

Date received by IBC _____

Date approved